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TITLE: Acceptance of Referral for Cancer-Risk Counseling in  
Population of Women Undergoing Breast Biopsy: Variables  
Predicting Followup at a Cancer Genetics Program

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## Introduction

Comprehensive breast cancer risk assessment using a synthesis of statistical models, pedigree analysis, detailed medical and exposure histories, and empiric research findings has traditionally been done in cancer genetic counseling and research settings. Clinically, enumeration of risk parameters varies and may or may not result in referral to specialists in comprehensive risk assessment. This study demonstrated use, in two clinical settings (breast biopsy clinic and breast cancer treatment clinic), of a brief risk assessment based on computerized models to identify and refer women who might benefit from a more comprehensive risk assessment, and examined the factors that influence referred women to follow up with cancer risk counseling. One hundred and twenty women with no previous breast cancer were recruited in a breast biopsy clinic and ninety-one women with breast cancer were recruited in a medical oncology clinic.

All subjects had a brief risk assessment and those who met criteria for increased risk were referred for cancer genetic counseling. Questionnaires assessing knowledge and attitudes about breast cancer, cancer risk counseling, and genetic testing were completed. Psychological assessment was done using the Profile of Mood States and the Impact of Events Scale. Uptake of referral was monitored and follow-up questionnaires were completed by the 14 women who attended cancer risk counseling and 74 of the 92 women who did not follow-up on their referral.

The findings may help to provide a better understanding of the motivations that lead women to use cancer risk counseling and foster development of more effective clinical referral strategies and more widespread use of cancer risk counseling.

## Annual Summary

### From Approved Statement of Work

#### *Task 1. To finalize preparations for patient interviews*

- a. Preparation and approval of Institutional Review Board proposal and consent document
- b. *Modification of computerized risk program to include Berry-Aguilar- and Shattuck-Eidens models*  
Consultation with clinical staff of CBP and CGP to review protocols and incorporate
- c. Finalize compilation of behavioral measures instruments for administration to our population

#### **Completed in 1999**

#### *Task 2. To identify, through brief breast cancer risk assessment, women undergoing biopsy who are at increased risk for breast cancer and refer them to the Cancer Genetics Program for comprehensive risk assessment and possible genetic testing. (months 4-19)*

- a. Interview biopsy patients (estimated at 10 per week), recruit participants, administer pre-BRA questionnaires, perform BRA, and initiate referrals to CGP

**We recruited 120 women between June 1 and Dec 21 of 1999. (see Annual report July 1999-July 2000. ) Referral rates were higher than anticipated. The referral criterion was a 10-year Gail model risk twice that of the age-dependent population risk. Sixty-three of the 120 women who participated had risk levels that met the referral criteria (greater than or equal to twice the population risk) and were referred.**

**After transfer of the study to the treatment population (see Addendum) we recruited 91 women between July 26, 2000 and January 31, 2001. Forty three were referred for BRCA mutation risk greater than or equal to 10%.**

- b. Track referral uptake at CGP

**All new patient appointments made at the Cancer Genetics program were screened to identify study participants. Only one referred biopsy subject followed up with a consultation visit to the CGP. Thirteen of the 43 referred treatment patients attended the CGP.**

- c. Administer second questionnaire and psychological measures, perform cancer risk counseling (including comprehensive risk assessment) at CGP

**As stated above, 14 women followed up with a consultation at the CGP and completed second questionnaire set at that time. We attempted to contact the remaining 92 referred subjects, by telephone, to complete a second questionnaire assessing reasons for declining follow-up appointment, and a second psychological assessment. Fifty-one of the 62 referred biopsy non-attenders and 23 of the 30 treatment non-attenders completed the second interview.**

#### *Task 3. To identify outcomes of biopsy and genetic testing for mutational status*

- a. Obtain biopsy results from medical records (ongoing, months 4-16)

**Original estimates were that 20-30% of biopsy outcomes would be positive. Actual outcomes were slightly less than expected: Malignant Cancer Dx 9%, In Situ Cancer Dx (DCIS,LCIS) 10%**

*b. Obtain genetic testing results from CGP*

Ten of the thirteen referred patients had genetic testing. Results for 4 patients were still pending as of July 1, 2001.

*Task 4. To analyze predictors of CGP referral uptake, and finalize reports and dissertation*

*a. Statistical analyses will be performed*

We tabulated group characteristics (descriptive data) including socio-demographic variables, breast cancer and BRCA mutation risk levels, breast cancer knowledge and awareness levels, opinions of the benefits and drawbacks of genetic counseling and testing, and general and cancer-specific psychological distress, for the biopsy and treatment groups.

In the biopsy group we examined correlations of the above parameters with expressed desire to have genetic testing in order to identify predictors of interest in genetic testing. Spearman correlations and Mann-Whitney tests were used for continuous variables and  $\chi^2$  approximations and Fisher exact tests were used for categorical variables. We also identified predictors of intent to have genetic counseling in the future in the sub-group of referred subjects who completed follow-up interviews ( $n = 51$ ).

In the treatment group, we examined correlation of the above parameters with acceptance of genetic counseling in the treatment group using non-parametric methods to identify positive and negative predictor variables. We were not able to perform these analyses in the biopsy group because only one referred subject attended genetic counseling. We also examined predictors of intent to have genetic testing in the future among the sub-group of referred subjects who did not attend genetic counseling, but completed follow-up interviews ( $n = 23$ ).

*b. Final report and doctoral thesis will be prepared*

This document is the final annual summary. The doctoral dissertation was written during the spring and summer of 2001. The dissertation was successfully defended before the dissertation committee and an audience of university members and lay observers on July 18, 2001. The final document was submitted to the University of Pittsburgh Graduate School of Public Health in August 2001 and the doctoral degree in Human Genetics was awarded at that time. The dissertation has also been submitted to UMI Dissertations Publishing service. Several papers are planned for publication in academic journals and this work is in progress.

**Addendum:**

**Modification of Protocol**

Acceptance of referral for cancer risk counseling in a population of women undergoing breast biopsy: Variables predicting follow-up at a cancer genetics program

To

Acceptance of referral for cancer risk counseling in clinical populations: Variables predicting follow-up at a cancer genetics program.

In January of 2000, after the interim analysis and consultation with Drs. Wendy Rubinstein and Victor Vogel (principal thesis advisors) and the other members of my thesis committee, it was proposed that the original hypothesis would best be addressed by transferring recruitment to the breast cancer treatment population. Approval by the DOD and local IRB for this modification was finalized on June 14 2000. An extension of funding from February 2001 to August 2001 was granted.

**Additional training activities:**

I have attended numerous seminars, lectures, and research talks at the University of Pittsburgh and participate in a weekly multidisciplinary breast cancer case conference. In addition I have attended the following scientific meetings:

MARHGN regional conference Philadelphia PA\*  
 American Society of Human Genetics, San Francisco CA \*  
 Intercultural Cancer Council, Washington DC  
 American Society of Clinical Oncology, New Orleans  
 Univ. of Pitt. Cancer Institute annual retreat Johnstown PA\*  
 American Society of Human Genetics, Philadelphia PA \*  
 National Society of Genetic Counselors, Savannah, GA \*  
 San Antonio Breast Cancer Symposium, San Antonio TX \*

Sept 1999  
 Oct 1999 (funded by DOD)  
 Feb 2000  
 May 2000  
 Jul 2000  
 Oct 2000 (funded by DOD)  
 Nov 2000  
 Dec 2000

\* presenter

## **APPENDIX A: Key Research Accomplishments**

- Recruited 120 female subjects having breast biopsy at the Comprehensive Breast Program of University of Pittsburgh Cancer Institute and Magee-Womens Hospital.
- Performed computerized risk assessment, administered questionnaires
- Referred 63 subjects to Cancer Genetics Program of University of Pittsburgh Cancer Institute and Magee-Womens Hospital.
- Provided genetic counseling consultation to one follow-up patient
- Recontacted 51 referred patients to administer questionnaires ascertaining reasons for declining genetic counseling referral
- Submitted modification of study proposal to transfer protocol to the diagnosed breast cancer treatment population . Approval granted on June 14, 2000. An extension of funding from February 2001 to August 2001 was also granted.
- Recruited 91 female subjects having treatment for breast cancer in the medical oncology unit of the Comprehensive Breast Program of University of Pittsburgh Cancer Institute and Magee-Womens Hospital.
- Performed computerized risk assessment, administered questionnaires
- Referred 43 subjects to Cancer Genetics Program of University of Pittsburgh Cancer Institute and Magee-Womens Hospital.
- Provided genetic counseling consultation to 13 follow-up patients.
- Recontacted 23 referred patients to administer questionnaires ascertaining reasons for declining genetic counseling referral
- Completed statistical analyses of demographics, attitudes about and knowledge of breast cancer and genetics, and psychological measures
- Submitted four abstracts based on findings
- Successfully defended dissertation on July 18, 2001
- Completed final dissertation document in August 2001, Doctor of Philosophy in Human Genetics degree awarded
- Four papers for publication are planned and in preparation

## **APPENDIX B: REPORTABLE OUTCOMES**

### **Abstracts Submitted and Accepted:**

Brief breast cancer risk assessment at the time of breast biopsy O'Neill SM, Peters JA, Feingold E, Ferrell RE, Vogel VG, Rubinstein WS.

Abstract # 1381 50th Annual Meeting of the American Society of Human Genetics, October 3-7, Philadelphia, PA.

Emotional Disturbance at the Time of Breast Biopsy: Is This a Teachable Moment? O'Neill, Suzanne M., Davison, Deborah, Rubinstein Wendy S, Vogel Victor G.

Abstract# 216 23rd Annual San Antonio Breast Cancer Symposium Dec 6-10 San Antonio, Texas.

Risk-based referral to a clinical cancer genetics program: a study paralleling the real world of non-research covered service. S.M. O'Neill1, V.G. Vogel1, E. Feingold, R.E. Ferrell, J.A. Peters, W.S. Rubinstein.

Abstract # 1442 2001 Annual Meeting of the American Society of Human Genetics, October 13-16, San Diego, CA.

Psychological disturbance in the breast care clinic: Implications for the timing of risk assessment.

S. O'Neill, V. Vogel, J. Peters, E. Feingold, R. Ferrell, and W. Rubinstein

National Society of Genetic Counselors Annual Education Meeting, Washington D.C., November, 2001

### **Employment Applied for:**

February 2000 NCI-99-1718A Genetic Counselor NCI division of Clinical Genetics

Advanced to qualified applicant pool-not selected

August 2000 Employment search in progress

## Appendix C

### Abstracts Submitted

#### **Abstract # 1381 50th Annual Meeting of the American Society of Human Genetics, October 3-7 2000, Philadelphia, PA.**

Brief breast cancer risk assessment at the time of breast biopsy O'Neill SM, Peters JA, Feingold E, Ferrell RE, Vogel VG, Rubinstein WS. Comprehensive Breast Program, University of Pittsburgh Cancer Institute and Magee-Womens Hospital, Pittsburgh, PA, Cancer Genetics Program, University of Pittsburgh Cancer Institute and Magee-Womens Hospital, Pittsburgh, PA, Dept of Human Genetics, University of Pittsburgh, Pittsburgh, PA

Referral of high risk women to cancer genetic counseling services is unstandardized in general clinical populations, and little is known about the factors that influence women to follow-up with such referrals. A brief quantitative breast cancer risk assessment using computerized statistical models may be a useful method for identification of referral candidates. , but information is needed about the breast cancer patient's attitudes regarding timing of, or interest in, the genetic counseling intervention.

This study followed 100 women attending a comprehensive breast program for fine needle, core, and stereotactic breast biopsies. A brief breast cancer risk assessment was done using the Gail and Claus models, questionnaires measuring knowledge, attitudes, and feelings about breast cancer, cancer risk counseling, and genetic testing were completed, and psychological assessments using the Profile of Mood States (POMS) and the Impact of Events Scale (IES) were done. Subjects with a calculated risk  $\geq$  twice the population risk were offered referrals to the Cancer Genetics Program (CGC) for comprehensive risk assessment and counseling. Referred subjects were contacted at 3-6 months post-biopsy to assess intention to follow-up with the CGP referral.

The majority of the study population was relatively young (mean =48) and of relatively high socioeconomic status, with 67% having at least some college and 70% having annual incomes above \$40,000. Almost all had health insurance (96%) and 92% reported a strong or moderately strong support system. Thirty seven percent reported a first or second degree relative with breast cancer and 53% had risk levels warranting referral. The mean Gail 10yr risk was 3.9% . Only two women had mutation carrier probabilities above 10%. In contrast to previous studies on risk perception, 85% of women in this population estimated their risk to be at or below average. Although only one woman followed through with a referral appointment, 46% stated that they would consider genetic counseling in the future, while 28% said they were not sure. The primary reason for declining referral was that subjects had obtained enough information about their risk from the brief risk assessment (40%) or from their doctors (49%). Forty percent cited "low risk" and 31% cited no family history as reasons for not following up on the referral.

Objective risk, as calculated by statistical models may not be a sufficient motivation for seeking cancer risk counseling at a genetic-based program. Although a large percentage of women indicated they definitely would or might seek such counseling in the future, many indicated that they would wait for some precipitating event, such as another biopsy or request of an offspring. This suggests that immediacy of threat may have a strong influence on referral uptake. However, for those women at increased risk, information and education is provided at a possible "teachable moment" and may have an influence on future behavior, either in the surveillance arena or in eventual participation in genetic counseling.

## Appendix C: continued

**Abstract# 216 23rd Annual San Antonio Breast Cancer Symposium Dec 6-10 2000, San Antonio, Texas.**

**Emotional disturbance at the time of breast biopsy: Is this a teachable moment?** \*O'Neill SM, Davison D, Vogel VG, Rubinstein WS. Comprehensive Breast Program, University of Pittsburgh Cancer Institute and Magee-Womens Hospital, Pittsburgh, PA, Cancer Genetics Program, University of Pittsburgh Cancer Institute and Magee-Womens Hospital, Pittsburgh, PA

It is assumed that breast biopsy is an anxiety-producing event for most women. However, it has been shown that moderate anxiety can be a motivating factor in assuming proactive health behaviors, such as increased screening and surveillance, and that a primary self-reported need of women undergoing breast biopsy is information and education about their future risk. This study followed 100 women attending a comprehensive breast program for fine needle, core, and stereotactic breast biopsies. In addition to questionnaires measuring breast cancer knowledge, attitudes, and feelings, subjects completed two psychological assessments; the Profile of Mood States (POMS) and the Impact of Events Scale (IES). A breast cancer risk assessment was also done using the Gail and Claus models.

Subjects were relatively young (mean=48y), predominantly Caucasian (95%), college-educated (50%), and married (71%), with 75% reporting a very strong support system. Thirty seven percent reported a first or second degree relative with breast cancer. The mean total mood disturbance score on the POMS was 16, a score higher than the normative scores reported for psychiatric outpatients. Highest scores were reported for the tension/anxiety (8), fatigue (5.1), and confusion (4.8) dimensions. The mean score on the IES for intrusive thoughts and cognitive avoidance relating to the breast biopsy were 11, and 10.9 respectively; scores approaching those of actual cancer patients. Follow-up administrations of the POMS and IES at 3-6 months post-biopsy resulted in a return to normal for most women. Women who received negative biopsy results indicated that they "did not want to think about breast cancer anymore". While time of biopsy may not be optimal for presenting complex educational information, referral algorithms outlining next-step scenarios may be optimally presented at this time.

## Appendix C: continued

**Abstract # 1442 2001 Annual Meeting of the American Society of Human Genetics, October 13-16, San Diego, CA.**

**AUTHORS** S.M. O'Neill<sup>1,2</sup>, V.G. Vogel<sup>1</sup>, E. Feingold<sup>2</sup>, R.E. Ferrell<sup>2</sup>, J.A. Peters<sup>3</sup>, W.S. Rubinstein<sup>4</sup>.

**INSTITUTIONS** 1) Comprehensive Breast Program and Cancer Genetics Program, UPCI/Magee Womens Hospital, Pittsburgh, PA; 2) Dept. of Human Genetics, University of Pittsburgh, PA; 3) Clinical Genetics Branch, NCI, Rockville, MD; 4) Evanston Northwestern Healthcare, Northwestern University Medical School, Chicago, IL.

**TITLE** Risk-based referral to a clinical cancer genetics program: a study paralleling the real world of non-research covered service.

**ABSTRACT** Genetic counseling and testing for BRCA mutations is a prototype for other common adult-onset disorders. We assessed uptake of a cancer genetics program (CGP) referral not covered by research funds in 211 subjects given a computerized breast cancer risk assessment (BRA) in the biopsy and treatment clinics of an urban women's hospital. Subjects completed questionnaires assessing psychological status and knowledge and attitudes about breast cancer (BC), cancer risk counseling, and genetic testing. Of 120 women with no previous history of BC undergoing breast biopsy, 63 (53%) were referred to the CGP on the basis of a Gail or Claus model risk <sup>3</sup>twice the population risk. Of 91 BC patients, 43 (47%) were offered referrals for a mutation risk <sup>3</sup>10% based on the Couch, Shattuck-Eidens, Frank, or BRCAPRO statistical models. At 6-18 months post-referral, only 1/63 unaffected, but a greater proportion (13/43; 30%) of affected, women made CGP appointments, and 10 had testing. Of the decliners, 74 were re-interviewed to elicit reasons for lack of follow-up. Main reasons cited by unaffected women included perceived low risk after benign biopsy results, lack of family history, and satisfaction with the BRA. Affected women cited a dissimilar spectrum of reasons: lack of time, sufficient risk information from their physicians and the BRA, and fear of insurance discrimination. High income was the greatest predictor of uptake ( $p = 0.006$ ). "Not wanting anymore tests" was a significant barrier ( $p = 0.03$ ). Most women (81%) said genetic risk assessment should be routine, suggesting annual mammography or OB/GYN visits as the most effective setting. Studies to date have focused on uptake of genetic testing offered to women as part of cost-free research studies. Uptake of referral may be less in the clinical arena and may depend on timing or setting of the referral.

## Appendix C: continued

### **Abstract submitted to National Society of Genetic Counselors Annual Education Meeting, Washington D.C., November, 2001**

Psychological disturbance in the breast care clinic: Implications for the timing of risk assessment.

S. O'Neill, V. Vogel, J. Peters, E. Feingold, R. Ferrell, and W. Rubinstein

Cancer Genetics Program of the University of Pittsburgh Cancer Institute and Magee Womens Hospital, Pittsburgh, PA

While there is growing recognition of the benefit of cancer genetic counseling services in medical practice, mechanisms for referral are neither well defined nor uniformly implemented. Our aim was to introduce genetic risk assessment into breast care settings, refer those at increased risk for breast cancer to genetic counseling, and determine the factors that motivate an individual to accept or decline a referral to genetic counseling.

We explored the use of brief computer-based risk assessment, as a mechanism to screen for referral to a cancer genetics program and measure subsequent uptake, in 271 women attending mammography, biopsy, and treatment clinics in a hospital-based comprehensive breast program. To assess psychological state at the time of the risk assessment, we administered the Profile of Mood States (POMS) to women undergoing screening mammograms ( $n=60$ ), having breast biopsies ( $n=118$ ), and having cancer treatment or follow-up ( $n=90$ ). Mean total mood disturbance scores (TMD) on the POMS were  $< 1$ , 17.4, and 16.9 respectively. The POMS scores for the biopsy and treatment groups were both greater than reported norms for psychiatric outpatient populations. The Impact of Events Scale (IES), a measure of event-related stress, was completed by women in the biopsy and treatment arms; total Avoidance scores were 15.8 and 12.5, total Intrusion scores were 11.7 and 11.4, respectively. At 6-9 month follow-up, all scores for those in the biopsy group (with benign findings) dropped significantly. The treatment group scored significantly lower in only the avoidance measure.

While women undergoing screening mammography had little mood disturbance, unaffected women undergoing diagnostic biopsies had high psychological stress levels similar to women who were being treated for breast cancer. Their avoidance scores were significantly higher ( $p=.015$ ) than those of women in treatment. This finding has implications for the provision of routine genetic services in the biopsy clinic setting. While for most women, a risk assessment may prove reassuring (since risk is often overestimated), for the high risk woman it may add an additional psychological burden at a fragile time. In addition, psychological disturbance may have an impact on an individual's ability to fully comprehend and absorb complex information. For many women, risk assessment at another time may be more productive.